

9 and 10 of the Queen patent. Applicants have fully complied with the requirements of 35 USC §135(b) in claiming substantially the same subject matter directed to the same invention as that claimed in the Queen patent prior to one year from the 12/17/96 date the Queen patent was granted.

(b) Presentation of a Proposed Count

Applicants present in Appendix A attached hereto the "Proposed Count." In compliance with 37 CFR §1.606, proposed Count 1 is broader than any of claims 1-4, the broadest claims in the Queen patent, and as broad as any one of claims 24-31 being entered into the instant application.

The proposed count contains disjunctive or alternative language to cover the claim terminology of the two parties. Such counts were expressly approved by the Board in *Hsing v. Myers*, 2 USPQ2d 1861 (Bd. Pat., App. & Int. 1987). It is clear, however, that both alternatives are directed to the same invention as that claimed in the Queen patent.

For Queen's term, "Chothia CDRs", applicants' claims and the proposed count paragraph (b) use the alternative term "the structural loop CDRs of the variable regions." In the Queen patent (at col. 11, lines 38-44) it is stated that the light or heavy chain variable regions consist of a "framework" region interrupted by three "hypervariable regions, also called CDRs."

In Chothia et al., *J. Mol. Biol.* (1987) 197, pp.901-917,

the authors (at p. 904) define their "loops" as having "somewhat different" limits from those of the CDRs defined by Kabat et al. (1983). Chothia et al. (at page 904) describe six loops in the domains L1, L2, L3, H1, H2, and H3¹, and use the descriptive terms "hairpin loops" (Fig.1), "hairpin turns" (Table 2), and "hypervariable loops" (p.903) to describe their regions which Queen has chosen to call "Chothia CDRs". A copy of the Chothia et al. publication is enclosed.

(c) Identification of Claims Corresponding to the Count

Applicants identify all of the Queen patent claims 1-11 and applicant's claims 24-27 as corresponding to the Count and as being directed to the same patentable invention.

(d) Application of the Terms of Applicants' Disclosure to the Copied Claims

In attached Appendix B, applicants illustrate the representative support in their present application disclosure for the limitations of their claims 24-27, substantially copied from Queen claims 1, 5, 9 and 10. There is, of course, additional support in applicants' application omitted for the sake of brevity.

(e) Applicants' Effective Filing Date

Applicants' present application, being a Rule 60 continuation, has the identical specification and drawings as

¹ In Fig. 1 of Chothia et al., these six domains are referred to as the "hypervariable regions."

that originally filed in U.S. application Serial No. 08/303.569, filed September 7, 1994, which is a U.S. national phase application stemming from PCT/GB-90/02017, filed December 21, 1990. The latter PCT application claimed priority benefit of GB national application Serial No. 89/28874.0, filed December 21, 1989. Enclosed is a copy of the GB application Serial No. 89/28874.0, a certified copy of which is on file in the aforesaid PCT/GB application.

In attached Appendix C is a diagram of support in applicants' 1989 GB application for each limitation of applicants' claims 28-31, which are also drawn to the same invention as proposed Count 1. Accordingly, applicants' effective filing date for their invention of Count 1 is 12/21/89, the filing date of their GB national application.

(f) Queen's Effective Filing Date

The Queen patent stems from U.S. Serial No. 08/477,728, filed June 7, 1995, which is a continuation of Serial No. 07/634,278, filed 12/19/90, which is a c-i-p of Serial No. 07/590,274, filed 9/28/90, and Serial No. 07/310,252, filed 2/13/89, which is a c-i-p of Serial No. 07/290,975, filed 12/28/88.

A careful study of Queen's 1988 and 1989 application disclosures reveals that that there is no disclosure therein for

certain critical limitations of the Queen patent claims and the proposed count, e.g., for the count limitation:

...said humanized immunoglobulin comprises amino acids from the donor immunoglobulin framework outside: (a) the Kabat and Chothia CDRs, or (b) both the Kabat CDRs and the structural loop CDRs of the variable regions,....

Neither of the Queen 1988 and 1989 applications contains any disclosure that teaches or suggests the requirement of amino acids from the donor Ig outside both the Kabat CDRs and structural loop (or Chothia) CDRs. This is a material limitation that was added to its claims by Queen to overcome the teachings of the prior art.²

The most that can be argued is that the 1988 and 1989 disclosures may be read to suggest that such amino acids are outside the Kabat CDRs; but nothing therein suggests that such amino acids also be outside the structural loop (or Chothia) CDRs. Thus, the absence of a disclosure of that presently claimed limitation in the earlier-filed Queen applications is clearly fatal to any attempt by Queen to claim priority benefit thereof.

While applicants have been unable to locate a copy of the Queen application allegedly filed on 9/28/90 to evaluate its

² In Queen's amendment of May, 31, 1996, at page 5, it was argued that the claims distinguish over the prior art because the immunoglobulins contain donor amino acids "outside the Kabat and Chothia CDRs."

disclosure, that application date is almost nine months later than the 12/21/89 filing date of applicants' GB application.

Queen should not be entitled to priority benefit of any application filed prior to 12/19/90, for the invention of Count 1 or its patent claims. Moreover, applicants do not concede that either the 12/19/90 application, or the application that matured into the Queen patent, contains an adequate disclosure of the invention of the proposed count. However, that issue need not be considered at this time.

Compliance With 37 CFR §1.608

Since applicants have the earlier effective filing date, there is no requirement for them to establish a prima facie case of earlier priority under §1.608.

The Requested Interference Should Be Declared

In applicants' parent application Serial No. 08/303,569, Queen's assignee, Protein Design Labs, Inc. ("PDL") has filed a Protest under 37 CFR §1.248. Therein, PDL specifically states (at page 2):

[A]n interference analysis should be undertaken by the appropriate Examiner....

Thus, PDL acknowledges that there is interfering subject matter in the parties' respective applications. For that reason, applicants have filed the present application with claims specifically directed to the claimed ssubject matter of the Queen patent. This paper more accurately characterizes the effective

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filing dates of the parties and shows that Queen would be the junior party of any interference declared hereon.

Applicants respectfully request that the proposed interference be promptly declared. MPEP §2307 states as follows:

Examiners should note that 37 CFR 1.607 requires that examination of an application in which applicant seeks an interference with a patent "shall be conducted with special dispatch." See MPEP §708.01 (emphasis added herein).

Applicants wish to point out that in their efforts to provoke the interference, claims 1, 5, 9 and 10 of the Queen patent were substantially copied. Thus, most claim limitations are those that were examined and approved by the Examiner who allowed the Queen patent. Should the present examination involve rejections of applicants' claims that would have been equally applicable against the Queen claims, applicants respectfully note MPEP §2307.02, which requires the approval of the Group Director for such a rejection. Applicants are presumptively the prior inventors of the claimed subject matter and only desire an interference to prove that they are the actual prior inventors. Their opportunity to do so should not be unduly delayed.

Enclosed is a copy of an Information Disclosure Statement filed in applicants' parent Serial No. 08/303,569, filed 9/7/94, and Serial No. 07/743,929. Copies of the references are in said parent applications.

Please contact applicants' attorney, Francis A. Paintin, at 215-568 3100 if he can be of assistance in expediting this request.

Respectfully submitted,

Francis A. Paintin
Francis A. Paintin
Registration No. 19,386

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WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

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